

Brief Summary of Prescribing Information

For Animal Use Only NADA#141-342

Alfaxan® Multidose (alfaxalone 10 mg/mL)

Intravenous injectable anesthetic for use in cats and dogs.

BRIEF SUMMARY OF PRESCRIBING INFORMATION

This summary does not include all the information needed to use Alfaxan® Multidose safely and effectively. See full package insert for complete information.

CAUTION:

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

INDICATIONS:

Alfaxan® Multidose is indicated for the induction and maintenance of anesthesia, and for induction of anesthesia followed by maintenance with an inhalant anesthetic, in cats and dogs.

DOSAGE AND ADMINISTRATION (highlights): Please refer to the complete package insert for full prescribing and administration information before use of this product.

Administer by intravenous injection only. For induction, administer Alfaxan® Multidose over approximately 60 seconds or until clinical signs show the onset of anesthesia, titrating administration against the response of the patient. Rapid administration of Alfaxan® Multidose may be associated with an increased incidence of cardiorespiratory depression or apnea. Apnea can occur following induction or after the administration of maintenance boluses of Alfaxan® Multidose. The use of preanesthetics may reduce the Alfaxan® Multidose induction dose. The choice and the amount of phenothiazine, alpha2- adrenoceptor agonist, benzodiazepine or opioid will influence the response of the patient to an induction dose of Alfaxan® Multidose.

When using Alfaxan® Multidose, patients should be continuously monitored, and facilities for the maintenance of a patent airway, artificial ventilation, and oxygen supplementation must be immediately available.

Alfaxan® Multidose contains preservatives. Use within 28 days of first puncture. Any unused Alfaxan® Multidose remaining after 28 days should be discarded. Alfaxan® Multidose should not be mixed with other therapeutic agents prior to administration.

INDUCTION OF GENERAL ANESTHESIA:

CATS: Induction dose guidelines range between 2.2 - 9.7 mg/kg for cats that did not receive a preanesthetic, and between 1.0 - 10.8 mg/kg for cats that received a preanesthetic. The alfaxalone induction dose in the field study was reduced by 10 - 43%, depending on the combination of preanesthetics (dose sparing effect).

DOGS: Induction dose guidelines range between 1.5 - 4.5 mg/kg for dogs that did not receive a preanesthetic, and between 0.2 - 3.5 mg/kg for dogs that received a preanesthetic. The Alfaxalone induction dose in the field study was reduced by 23 - 50% depending on the combination of preanesthetics (dose sparing effect).

Dose sparing of Alfaxan® Multidose will depend on the potency, dose, and time of administration of the various preanesthetics that are used prior to induction. To avoid anesthetic overdose, titrate the administration of Alfaxan® Multidose against the response of the patient. The average Alfaxan® Multidose induction dose rates for healthy cats and dogs given alfaxalone alone, or when alfaxalone is preceded by a preanesthetic, are indicated in species specific tables found in the full package insert. These tables are based on field study results and are for guidance only. The dose and rate for alfaxalone should be based upon patient response.

MAINTENANCE OF GENERAL ANESTHESIA:

CATS and DOGS: Following induction of anesthesia with Alfaxan® Multidose and intubation, anesthesia may be maintained using intermittent Alfaxan® Multidose intravenous boluses or an inhalant anesthetic agent. Please review the full package insert for guidance on recommended intermittent doses of Alfaxan® Multidose and the expected duration of effect. Clinical response may vary, and is determined by the dose, rate of administration, and frequency of maintenance injections.

Alfaxan® Multidose maintenance dose sparing is greater in cats and dogs that receive a preanesthetic. Maintenance dose and frequency should be based on the response of the individual

patient.

Inhalant anesthetic maintenance of general anesthesia in cats and dogs: Additional low doses of Alfaxan® Multidose, similar to a maintenance dose, may be required to facilitate the transition to inhalant maintenance anesthesia.

WARNINGS:

Animal Safety: When anesthetized using Alfaxan® Multidose, patients should be continuously monitored, and facilities for the maintenance of a patent airway, artificial ventilation, and oxygen supplementation must be immediately available.

Rapid bolus administration or anesthetic overdose may cause cardiorespiratory depression, including hypotension, apnea, hypoxia, or death. Arrhythmias may occur secondary to apnea and hypoxia. In cases of anesthetic overdose, stop Alfaxan® Multidose administration and administer treatment as indicated by the patient's clinical signs.

Cardiovascular depression should be treated with plasma expanders, pressor agents, anti-arrhythmic agents or other techniques as appropriate for the treatment of the clinical signs.

Human Safety: Not for human use. Keep out of the reach of children.

Alfaxan® Multidose should be managed to prevent the risk of diversion, through such measures as restriction of access and the use of drug accountability procedures appropriate to the clinical setting.

Exercise caution to avoid accidental self-injection. Overdose is likely to cause cardiorespiratory depression (such as hypotension, bradycardia and/or apnea). Remove the individual from the source of exposure and seek medical attention. Respiratory depression should be treated by artificial ventilation and oxygen.

Avoid contact of this product with skin, eyes, and clothes. In case of contact, eyes and skin should be liberally flushed with water for 15 minutes. Consult a physician if irritation persists. In the case of accidental human ingestion, seek medical advice immediately and show the package insert or the label to the physician.

The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information.

To report adverse reactions in users or to obtain a copy of the MSDS for this product call 1-844-253-2926.

DRUG ABUSE AND DEPENDENCE:

Controlled Substance: Alfaxan® Multidose contains alfaxalone, a neurosteroid anesthetic and a class IV controlled substance.

Abuse: Alfaxalone is a central nervous system depressant that acts on GABA receptor associated chloride channels, similar to the mechanism of action of Schedule IV sedatives such as benzodiazepines (diazepam and midazolam), barbiturates (phenobarbital and methohexital) and fospropofol. In a drug discrimination behavioral test in rats, the effects of alfaxalone were recognized as similar to those of midazolam. These biochemical and behavioral data suggest that alfaxalone has an abuse potential similar to other Schedule IV sedatives.

Physical dependence: There are no data that assess the ability of alfaxalone to induce physical dependence. However, alfaxalone has a mechanism of action similar to the benzodiazepines and can block the behavioral responses associated with precipitated benzodiazepine withdrawal. Therefore, it is likely that alfaxalone can also produce physical dependence and withdrawal signs similar to that produced by the benzodiazepines.

Psychological dependence: The ability of alfaxalone to produce psychological dependence is unknown because there are no data on the rewarding properties of the drug from animal self-administration studies or from human abuse potential studies.

PRECAUTIONS:

Rapid arousal: Careful monitoring of the patient is necessary due to possibility of rapid arousal.

Preanesthesia: Benzodiazepines may be used safely prior to Alfaxan® Multidose in the presence of other preanesthetics. However, when a benzodiazepine was used as the sole preanesthetic, excitation occurred in some dogs and cats during Alfaxan® Multidose anesthesia and recovery.

Apnea: Apnea may occur following administration of an induction dose, a maintenance dose or a dose administered

during the transition to inhalant maintenance anesthesia, especially with higher doses and rapid administration.

Endotracheal intubation, oxygen supplementation, and intermittent positive pressure ventilation (IPPV) should be administered to treat apnea and associated hypoxemia.

Blood Pressure: The myocardial depressive effects of Alfaxan® Multidose combined with the vasodilatory effects of inhalant anesthetics can be additive, resulting in hypotension. Preanesthetics may increase the anesthesia effect of Alfaxan® Multidose and result in more pronounced changes in systolic, diastolic, and mean arterial blood pressures. Transient hypertension may occur, possibly due to elevated sympathetic activity.

Body Temperature: A decrease in body temperature occurs during Alfaxan® Multidose anesthesia unless an external heat source is provided. Supplemental heat should be provided to maintain acceptable core body temperature until full recovery.

Breeding Animals: Alfaxan® Multidose has not been evaluated in pregnant, lactating, and breeding cats. Alfaxalone crosses the placenta, and as with other general anesthetic agents, the administration of alfaxalone may be associated with neonatal depression.

Kittens and Puppies: Alfaxan® Multidose has not been evaluated in cats less than 4 weeks of age or in dogs less than 10 weeks of age.

Compromised or Debilitated Cats and Dogs: The administration of Alfaxan® Multidose to debilitated patients or patients with renal disease, hepatic disease, or cardiorespiratory disease has not been evaluated. Doses may need adjustment for geriatric or debilitated patients. Caution should be used in cats or dogs with cardiac, respiratory, renal or hepatic impairment, or in hypovolemic or debilitated cats and dogs, and geriatric animals.

Analgesia during anesthesia: Appropriate analgesia should be provided for painful procedures.

ADVERSE REACTIONS:

The primary side effects of alfaxalone are respiratory depression (apnea, bradypnea, hypoxia) and cardiovascular derangements (hypertension, hypotension, tachycardia, bradycardia). Other adverse reactions observed in clinical studies include hypothermia, emesis, unacceptable anesthesia quality, lack of effectiveness, vocalization, paddling, and muscle tremors. To report adverse reactions or obtain a copy of the SDS for this product call 1-844-253-2926.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

OVERDOSE: Rapid administration, accidental overdose, or relative overdose due to inadequate dose sparing of Alfaxan® Multidose in the presence of preanesthetics may cause cardiopulmonary depression. Respiratory arrest (apnea) may be observed. In cases of respiratory depression, stop drug administration, establish a patent airway, and initiate assisted or controlled ventilation with pure oxygen. Cardiovascular depression should be treated with plasma expanders, pressor agents, antiarrhythmic agents or other techniques as appropriate for the observed abnormality.

HOW SUPPLIED:

Alfaxan® Multidose is supplied in 10 mL and 20 mL multiple-dose vials containing 10 mg alfaxalone per mL. Manufactured in Australia by: Jurox Pty Ltd.

Marketed by:
Jurox Inc.
Kansas City, MO 64111
Phone: 1-844-253-2926

Distributed by:
Vedco, Inc.
St Joseph, MO 64507

Alfaxan is a registered trademark of Jurox Pty Limited.

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US Patent # 9492552